

Remarks

The preliminary amendment submitted on September 8, 2003 was inadvertently not reflected in the substitute specification submitted on October 13, 2006. Therefore, the specification is being amended to reflect the amendments included in the preliminary amendment submitted on September 8, 2003. The title has been amended and the second paragraph after example 15 has been amended to reflect the amended versions included in the preliminary amendment. In addition, the cross-reference to related applications is being added, but differs from the version in the preliminary amendment, as the parent application has now issued as a U.S. Patent.

In the specification, the paragraph beginning at page 22, line 22 and extending to page 24, line 12 of the substitute specification has been amended to correct minor errors as well as the footnote to Table 3 at the top of page 37 of the substitute specification. Also, the paragraph following Example 27 of the substitute specification has been amended to include generic terminology for trademarked materials.

Claims 35-40, 43-54, and 59-62 are pending in this application. Claims 35-37, 43-47, and 59-62 have been rejected. Claims 38-40 and 48-54 have been withdrawn. Claim 54 has been amended.

Objections to the Specification:

The Examiner has noted the use of trademarks in the application and has requested that they should be capitalized and that the generic terminology accompany any trademarks. The amendments to the specification correctly identify the drugs captopril, cilazapril, lisinopril, and lovastatin as the generic names for these compounds. In addition, the generic terminology for the trademarked materials are identified for Example 27. The applicants

believe that all of the trademarks have been correctly identified. Furthermore, the applicants would like to respectfully point out that the Examiner indicated as much in her advisory action mailed on October 24, 2006. Applicants respectfully request the withdrawal of the objections to the specification.

Rejections under 35 U.S.C. § 112

The Examiner has rejected claims 35-37, 43-47 and 59-62 under 35 U.S.C. § 112, first paragraph as lacking enablement. The Examiner states that “[o]f the 28 examples in the specification, only Examples 21-25 have particles in a diffusion layer, and none of these have a first region and a second region, with the particle volume fraction greater in the first region.”

Applicants respectfully traverse the Examiner’s rejection for at least the following reasons.

First, as noted in MPEP 2164.02, an example is not required for enablement. “Compliance with the enablement requirement of 35 USC 112 first paragraph, does not turn on whether an example is disclosed.” Thus, the fact that only Examples 21-25 include particles is not pertinent to enablement.

Second, applicants assert that claims 35-37, 43-47 and 59-62 are enabled. Figure 2C and its related description clearly show a first region, 28B, of a barrier having a greater particle volume fraction from the second region, 28A, of a barrier. In addition, lines 1-5 of page 40 of the substitute specification read as follows: “In accordance with one embodiment, more particles are deposited in the polymer for diffusion barrier layer 28 B. Accordingly, the packing density or particle volume fraction for diffusion barrier layer 28B is greater than the packing density for

diffusion layer 28A.” Also, page 40, lines 9-10 recite “[a]lternatively, for a higher packing density, particles 30B can, for example, be of greater size than particles 30A.” Moreover, a masking method to make the embodiment of the claim is recited at lines 21-23 of page 39, and line 1 of page 40 of the substitute specification which read as follows: “First and second reservoir layers 34A and 34B are covered by first and second diffusion barrier layers 28A and 28B, respectively. Such selective patterning can be achieved by, for example, masking the designated regions prior to the application of the composition.”

Third, applicants would like to point out that claims 59-62 were previously rejected under 35 U.S.C. § 112 in the February 1, 2006 office action, and the Examiner withdrew that rejection in her August 21, 2006 final office action. Furthermore, in the advisory action of December 4, 2006, the Examiner indicated that claims 59-62 were allowed. Claims 59-62 have not been amended since the Examiner withdrew her rejection in the August 21, 2006 office action. Thus, the applicants ask why the Examiner has waited until after a request for continued examination has been filed in this case to make this rejection?

Moreover, the applicants would like to respectfully point out that a rejection that is not necessitated by either claim amendments or new references, and which occurs this late in the prosecution of the application, is improper. MPEP § 706 states “[t]he goal of examination is to clearly articulate any rejection early in the prosecution process so that the applicant has the opportunity to provide evidence of patentability and otherwise reply completely at the earliest opportunity.” As this rejection was not based upon the discovery of new art or claim amendments, applicants assert that the Examiner should have raised this rejection not later than at the time that she made her other 35 U.S.C. § 112 rejection in the February 1, 2006 office action.

Thus, applicants respectfully request the withdrawal of the 35 U.S.C. § 112, first paragraph rejection with respect to independent claim 59, and dependent claims 35-37, 43-47 and 60-62.

The Examiner has rejected claim 36 under 35 U.S.C. § 112, second paragraph as being indefinite. In particular, the Examiner has asserted that “it is not clear what is meant by ‘main group oxides.’”

Applicants respectfully traverse the Examiner’s rejection for at least the reason that the term “main group oxide” has a defined scientific meaning that is readily available to one skilled in the art. Applicants cite Wikipedia, the free encyclopedia, which defines the main group elements as follows: “In chemistry and atomic physics, main group elements are elements in groups, (periodic columns) whose lightest members are represented by hydrogen, beryllium, boron, carbon, nitrogen, oxygen, fluorine, and helium as arranged in the periodic table of elements. Main group elements include elements in groups 1, 2, and 13-18.” Oxides are generally defined as a binary compound of an element or radical and oxygen. Thus, main group oxides are oxides of the main group elements. As additional evidence that the term “main group oxides” has a well established scientific meaning, a citation to a communication in a journal has been provided (Exhibit A) which includes the term “main group oxides” in the title.

As applicants have provided evidence that “main group oxides” has a defined scientific meaning, applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 112, second paragraph rejection of claim 36.

Rejections under 35 U.S.C. § 103

The Examiner has rejected claims 35-37, 43-45, 47 and 59-62 under 35 U.S.C. § 103(a) as being obvious over Wu et al., United States Patent 6,805,898 (“Wu”). Furthermore, the Examiner has rejected claim 46 under 35 U.S.C. § 103(a) as being obvious over Wu in view of Pacetti et al., United States Patent 6,355,058 (“Pacetti”).

Applicants respectfully traverse the Examiner’s rejection under 35 U.S.C. § 103(a).

The present application, application 10/658,348, is a divisional application of United States Patent application 09/750,515 filed on December 28, 2000, which has since issued as United States patent 6,663,662. As per MPEP 706.02(V)(A), the effective filing date of a divisional application is the earliest filing date in the line of the divisional. Therefore, the present application has an effective filing date of December 28, 2000.

Effective November 29, 1999, subject matter which was prior art under former 35 U.S.C. §103 via 35 U.S.C. §102(e) is now disqualified as prior art against the claimed invention if that subject matter and the claimed invention, “were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person” (see MPEP Section 706.02(I)(1)). A statement of an attorney of record can be sufficient evidence to establish common ownership (see MPEP Section 706.02(I)(2)(II)). As established by the enclosed Statement of Common Ownership (Exhibit B), at the time the inventions of the current application were made, the inventions of the current application and Wu were owned by, or subject to an obligation of assignment to, Advanced Cardiovascular Systems, Inc., a California corporation. Since the Applicants have established common ownership, Wu is disqualified as prior art and should be removed as a reference. Accordingly, claim 59 is allowable, and claims 35-37, 43-47 and 60-62 are allowable for at

least the reason that claim 59 is allowable. Applicants respectfully request the withdrawal of the rejections to claims 35-37, 43-47 and 59-62.

Furthermore, although the rejection of claim 46 is moot in light of the removal of Wu, applicants would like to point out that Pacetti should also be removed as it is also a commonly owned application. If requested by the Examiner, applicants can also supply a statement of common ownership with respect to Pacetti.

Applicants respectfully submit that the pending claims are in condition for allowance.

MPEP § 821.04 recites the following:

The propriety of a restriction requirement should be reconsidered when all the claims directed to the elected invention are in condition for allowance, and the nonelected invention(s) should be considered for rejoinder. Rejoinder involves withdrawal of a restriction requirement between an allowable elected invention and a nonelected invention and examination of the formerly nonelected invention on the merits.

In order to be eligible for rejoinder, a claim to a nonelected invention must depend from or otherwise require all the limitations of an allowable claim.

Claim 59 is generic as the Examiner pointed out in her restriction/election requirement of February 12, 2007. Claims 38-40 and 48-54 depend from claim 59. Therefore, with respect to withdrawn claims 38-40 and 48-54, applicants respectfully request that the Examiner rejoin these claims and subsequently examine these claims on the merits.

Conclusion

Applicants respectfully submit that the pending claims are in condition for allowance. Applicant respectfully requests the Examiner to withdraw all rejections and allow claims 35-37, 43-47, and 59-62. With respect to withdrawn claims 38-40 and 48-54, applicants request that the Examiner rejoin these claims. Should the Examiner have any other issues, applicants request that the Examiner call the undersigned attorney of record to expedite the closure of this application.

The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. **07-1850**.

Respectfully submitted,

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APPENDIX